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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,546	02/16/2001	Sonya Franklin	875.037US1	5198
21186	7590	03/17/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/785,546	FRANKLIN, SONYA	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003 and 01 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 3, 19-26 and 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-18, 27-29 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/03 and 3/1/04 have been entered.

Claims 3, 19-26 and 30-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

The disclosure is objected to because of the following informalities:

On page 8, lines 22-23, colors are mentioned. The figures filed 10/15/01 do not have colors. Applicant has now corrected the mention of colors on lines 20-21 and 27-28 but did not correct them here.

Appropriate correction is required.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is incorrect in the recitation of "binds a lanthanide...", which should apparently be "which binds a lanthanide..."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear,

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concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-18, 27-29 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection. This rejection is repeated for essentially the reasons given in the last action. Applicant's arguments have been carefully considered but do not overcome the instant rejection.

It is maintained that at the very least the claims should be limited to the EuP3, EuP4 and EuP5 structures where P3 and P4a are SEQ ID NO:2 and 4 and this examination was restricted so as to be limited to SEQ ID NO:2. It is not clear what the identity of "Eu5L" is nor what the SEQ ID NO: of "5L" is. An explanation is required. The examiner is not saying that claims of this scope would be allowed, but is stating that apparently nothing else is shown in the specification to cleave DNA. Whether these structure cleave DNA is subject to explanations to the questions raised *infra*. The examiner has made a concerted effort to understand the instant invention by re-reading the entire specification in light of the various amendments and other submissions by applicants. The application is hard to understand and the examiner has made many requests for clarification in previous actions. As it is maintained that Figure 8 does not show cleavage of supercoiled DNA (discussed *infra*), the only evidence for possible cleavage of DNA is the data in Table 1.

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Looking at Table 1, the meaning of columns 3 and 4 is not fully understood. In the paper filed 1/21/03 applicants state that the two columns refer to "a EuP3 monomer and a singly occupied dimer, respectively (see page 48, lines 6-9 and page 54, line 1-2 and 14-16 of the specification) (basis 3)". The lines referred to on page 48 and page 54, lines 14-16 refer to "a singly occupied dimer (EuP3)" while the references to page 54, lines 1-2 do not refer to this at all. It is not know what was meant by "(basis 3)".

What does "a singly occupied dimer (EuP3)" mean and should the recitation not be "a singly occupied dimer (EuP3<sub>2</sub>)"? What is the dimer singly occupied by? On page 55, lines 22-25, a "Ca-binding motif" is referred to and the rate in Table 1 compared to this. The examiner cannot see any mention of a "Ca-binding motif" in Table 1. In the last column labeled "Rates", various values are present and it is not known what the significance of them is nor how they relate to the data in columns 2-4.

It is stated on page 56, lines 1-2 that "as shown in Figure 8, EuP3 catalyzes the cleavage of supercoiled, double-stranded DNA as well as model compounds". Does this eliminate EuP4a, and EuP5L? The examiner cannot discern any appreciable difference between lanes 6-9 and 10-15 except for the decrease in both "open circular" and "supercoiled" at the higher concentrations, which is explained in the legend to Figure 8 on page 10. Lanes 6-9 are DNA plus free P3 and lanes 10-15 are DNA plus Eu:P3. The figure is supposed to show the "conversion of supercoiled...to open circular...linear...or smaller fragments" (page 56, lines 2-4). The examiner cannot readily see a decrease in supercoiled or an increase in open circular and/or linear. Therefore it is maintained that this figure does not show that EuP3 cleaves supercoiled DNA.

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As stated previously, it is not understood how residues at one position, e.g. A at positions 43, can be substituted for R at position (19) as in the recitation of "A<sub>43</sub> → R<sub>(19)</sub>", and "Q<sub>44</sub> → E<sub>(20)</sub>" on pages 50-51. Applicant replied in the amendment filed 1/21/03 that this "indicates an alanine to arginine substitution at position 19 in a synthetic peptide of the invention which corresponds to the alanine residue at position 43 in the engrailed homeodomain (see Figure 2)...[and] a glutamine to glutamic acid substitution at position 20 in a synthetic peptide of the invention which corresponds to the glutamine residue at position 44 in the engrailed homeodomain". It was stated in the action replying to this amendment that this is not understood, however applicants have not further addressed this matter in their papers filed 1/29/03 or 3/1/04. How can this refer to an alanine at position 19 when the recitation is "A<sub>43</sub>"? This goes against the normal and accepted notations of amino acids at particular positions.

Claim 1 is drawn to a synthetic peptide with a DNA binding domain and a metal binding domain, "wherein the domain which specifically binds the metal is within the domain which specifically binds the nucleic acid sequence". Apparently nowhere in the specification is it taught that these two domains are the same. What is apparently taught is that the peptides disclosed in the specification will bind a metal and that possibly this complex will cleave a nucleic acid. It is not shown that the peptide "specifically binds a nucleic acid". Indeed, there is not shown to be anything "specific" for the nucleic acid cleavage, absent convincing proof to the contrary. Applicant has replied in the paper filed 1/21/03 that "the specification discloses that the DNA binding domain and the metal binding domain are substantially superimposable in the helix orientation, and so such a metal binding domain can be introduced to a DNA binding domain, e.g., by replacing the turn or

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loop in the DNA binding domain with the metal binding domain (page 3, lines 19-23)" and that "engrailed binds to a consensus sequence TCAATTAAAT". They replied in the amendment filed 12/29/03 "that the invention includes a nucleic acid binding domain and a metal binding domain (page 5, lines 8-10 and Figure 2)...[and that] the metallated peptide of the invention bound a plasmid with at least 11 partial target sequences for engrailed, while a control peptide did not (page 54, lines 21-24 and page 55, lines 9-10)" (emphasis in original). The indicated passage of page 5 states that "[t]he domain which specifically binds the metal is preferably within...the domain which specifically binds the nucleic acid sequence" and Figure 2 merely gives the sequences of 7 peptides. The indicated passage on page 54 merely states that pBR322 "contains three 5'TAATT-3' sequences, and eight 5'TAAT5' sequences", and the indicated passage on page 55 states that "[t]hese data indicate that the EuP3 binds DNA in the 20  $\mu$ M range". The recitations do not teach that the metallated peptide binds to these sequences and do not teach that the metal binding domain is within the nucleic acid domain. It is simply stated that it is "preferably" within this domain. There are no results in the specification showing that this is true.

With respect to enablement for only EuP3, EuP4 and EuP5, three references are submitted to consider. These references were all published after the instant application and do not enter into determining what is disclosed in the instant specification, absent convincing proof to the contrary.

For the reasons discussed *supra*, it is maintained that one of ordinary skill in the art would not know how to make and/or use the invention within the scope of the instant claims from reading the instant specification. It is also maintained that this ordinary artisan would have had no assurance

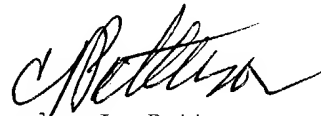
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that the applicant had possession of the invention at the time of filing of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
March 12, 2004